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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/970,453 | 10/02/2001 | Shulamit Eyal | 20174C-002410US | 9637 |
| 20350 | 7590 | 09/29/2005 | EXAMINER | |
| TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 | | | COOK, LISA V | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1641 | |

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,453

Applicant(s)

EYAL ET AL.

Examiner

Lisa V. Cook

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1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/22/05 has been entered.

Amendment Entry

2. Applicants' response to the Final Office Action mailed January 24, 2005 is acknowledged (paper filed 7/22/05). In response to Amendment filed therein the specification along with claims 1,4, 7, 10, 12, and 13 were modified. Claims 2, 5-6, 8-9 and 14-18 have been canceled at Applicants request.

3. Currently, claims 1, 3-4, 7, and 10-13 are pending and under consideration.

4. Objections and/or rejections of record not reiterated below have been withdrawn.

OBJECTIONS WITHDRAWN

Oath/Declaration

5. A new oath or declaration is required because provisional application number 60/237,937 filed 10/3/00 is not included and the corrected citizenship for inventor Eyal is not initialed and dated. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required.

The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Applicants have submitted a new Declaration on May 26, 2005. The substitute Declaration has been considered and was found acceptable. Accordingly this objection is withdrawn.

Specification

6. *Applicant has corrected the deficiencies noted below by amendment. Accordingly the following objection in items 7 and 8 below are withdrawn.*

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 9 line 1. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. This attempt to incorporate subject matter into the patent by reference is improper because PTO policy does not permit the PTO to link to any commercial sites since the PTO exercises no control over those organizations, views or accuracy of the information contained on those outside sites. Appropriate correction is required. See MPEP § 608.01.

8. The use of several trademarks is noted in this application. They should be capitalized wherever they appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. (For example, see pages 22,- YOYO-1).

Claim Objections

9. Claim 13 is objected to because of the following informalities: In claim 13 the word "an" appears to be missing. Step (A) line 5-6 read "parameter is [an] integrated peak are".

Appropriate correction is required.

Applicant has modified the claim to eliminate the deficiency in item #9 above. Therefore the objection is withdrawn.

OBJECTIONS MAINTAINED

Information Disclosure Statement

10. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or Applicant on PTO-1449 has cited the references they have not been considered.

11. The information disclosure statement filed 1/31/02 has been considered as to the merits prior to first action.

12. The supplemental information disclosure statement filed 6/18/04 has been considered as to the merits prior to final action.

Applicant has not addressed the objection with respect to the IDS. Accordingly the objection is maintained.

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1, 3, and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopf-Sill et al. (US Patent #6,613,512) or Kopf-Sill et al. (US Patent #6,524,790) in view of Kosaka Tokihiro (JP 07049301 A – English Abstract Only).

Kopf-Sill et al. disclose methods and microfluidic devices to measure reactants and reaction products while considering velocity. See column 1 line 64 through column 2 line 23.

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Reactants and products with different velocities (characteristics of an analyte) are measured in a microfluidic channel. See column 2 lines 36-37 and lines 57-58. In one embodiment the fluid samples are transported from a first position to a second position by electroosmotic flow (claim 4). See column 6 lines 15-18. The time dependent data generated is processed to include baseline subtraction and masking for accurate measurements of the analyte of interest (normalizing and considering velocity). See column 1 lines 64-67 and column 22 lines 18-42.

Multiple detection positions/zones are taught at two different time points in figure 1. See figure 1 Time= t_2 and Time>> t_2 (time difference measurement). The time difference and velocity are utilized in an equation to accurately measure the characteristic of interest in the analyte (claims 8 and 9). See column 5 line 11 through column 6 line 43. The various reactants and products can be assessed serially (individually) or simultaneously in the methods (claim 5). See column 2 lines 34-35. Kopf-Sill et al. teach the step of normalizing or eliminating the velocity component in reaction measurements. See column 5 lines 55-62 and column 8 lines 10-22.

Kopf-Sill et al. and Kopf-Sill et al. differ from the instant invention in not teaching sample detection at a plurality of detection zones between a first position (sample entry time) and a second position (sample end time).

However, Kosaka Tokihiro disclose a particle analyzer that achieves higher image resolution of moving particles at different points (detection zones). The particles are analyzed in the detection zones with sensors A1 and A2. The separately detected measurements are combined (half measurement from each) to achieve higher image resolution in a direction of the flow of the particles. (See abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use dual detection zones (plurality of different detection zones) as taught by Kosaka Tokihiro in either method of Kopf-Sill et al. (6,613,512 or 6,524,790) because Kosaka Tokihiro taught that dual detection zones achieved higher image resolution in a direction of the flow of the particles. (See abstract). One of ordinary skill in the art would have been motivated to utilize dual detection zones (plurality of different detection zones) in order to more accurately detect the particles of interest.

II. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kopf-Sill et al. (US Patent #6,613,512) or Kopf-Sill et al. (US Patent #6,524,790) in view of Kosaka Tokihiro (JP 07049301 A – English Abstract Only) as applied to claims 1, 3, and 4 above, and further in view of Squire et al. (Journal of Microscopy, 197(2) 2/2000, 136-149).

Please see Kopf-Sill et al. (US Patent #6,613,512) or Kopf-Sill et al. (US Patent #6,524,790) in view of Kosaka Tokihiro as set forth above.

Kopf-Sill et al. (US Patent #6,613,512) or Kopf et al.-Sill (US Patent #6,524,790) in view of Kosaka Tokihiro differ from the instant invention in failing to teach acousto-optic modulators.

However, Squire et al. teach methods for measuring fluorescence with wave acoustic-optic modulators placed in a series. This configuration analyzed multiple data sets simultaneously and distinctly. See abstract.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to use acoustic-optic modulators as taught by Squire et al. in either method of Kopf-Sill et al. (6,613,512 or 6,524,790) in view of Kosaka Tokihiro because Squire et al. taught that “standing wave acoustic-optic modulators provide a means of modulating a continuous wave laser in a sinusoidal manner at high frequencies.

A number of these [lasers] can be employed in series to simultaneously modulate the excitation light of individual frequencies, their differences, and sums.” See page 139 figure 2 and 2nd column last paragraph.

One of ordinary skill in the art would have been motivated to utilize these lasers in order to detect multiple frequencies simultaneously. Therein evaluating several analytes.

III. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopf-Sill et al. (US Patent #6,613,512) or Kopf-Sill et al. (US Patent #6,524,790) in view of Kosaka Tokihiro (JP 07049301 A – English Abstract Only) as applied to claims 1, 3, and 4 above, and further in view of Armstrong et al. (Cytometry, 40:102-108, 2/2000).

Please see Kopf-Sill et al. (US Patent #6,613,512) or Kopf-Sill et al. (US Patent #6,524,790) in view of Kosaka Tokihiro as set forth above.

Kopf-Sill et al. (US Patent #6,613,512) or Kopf et al.-Sill (US Patent #6,524,790) in view of Kosaka Tokihiro differ from the instant invention in failing to teach oligonucleotide detection including nucleotide measurements.

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However, Armstrong et al. teach this limitation. Their methods evaluate PCR probes that are linked to fluorescent molecules and measured by flow cytometry. See abstract. The method detects individual nucleotides from individual nucleotide fluorescence peaks. See figures 2, 3, and 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use detect oligonucleotides and the nucleotides which make up the oligonucleotides as taught by Armstrong et al. in either method of Kopf-Sill et al. (6,613,512 or 6,524,790) in view of Kosaka Tokihiro because Armstrong et al. taught that genetic diversity is exhibited in disease and drug response and they can be effected by a single nucleotide difference/change/variant. See abstract.

Response to Arguments

14. Applicant contends that the patents to Kopf-Sill (US Patent #6,613,512) and Kopf-Sill et al. (US Patent #6,524,790) do not anticipate the instant invention because they do not disclose the measuring of a characteristic parameter of an analyte within a fluid flow channel at a plurality of locations along the fluid flow channel. This argument was carefully considered and found persuasive. Accordingly, Kopf-Sill (US Patent #6,613,512) and Kopf-Sill et al. (US Patent #6,524,790) were combined with Kosaka Tokihiro to make the invention obvious.

With respect to the rejections under 35 USC 103(a), including Squire et al. (Journal of Microscopy, 197(2) 2/2000, 136-149) and Armstrong et al. (Cytometry, 40:102-108, 2/2000), Applicant contends that the additional references do not cure the deficiencies of Kopf-Sill. Kopf-Sill et al. have been addressed above. Therefore the rejections are maintained.

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15. For reasons aforementioned, no claims are allowed.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

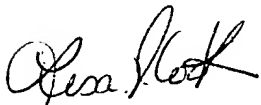
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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

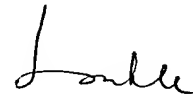


Lisa V. Cook
Patent Examiner

Art Unit: 1641

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09/26/05